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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,975	07/03/2003	Donald L. Wise	CSI 130	8618

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,975	WISE ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendments and response received 3/22/2004 is acknowledged. Claim 9 has been amended. Claims 12-21 have been canceled. The abstract has been amended. Specification pages 7 and 8 have been amended.

2. Currently claims 1-11 are pending and under consideration.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Information Disclosure Statement

4. Applicants' resubmission of information disclosure statement originally filed on October 28, 2003 is acknowledged. The references have been considered by the examiner, see attached PTO 1449.

Objections Withdrawn

5. Objection to abstract of disclosure made in paragraph 7 of the office action mailed December 22, 2003 is withdrawn in view of applicants' amendments.

Rejections Withdrawn

6. Rejection of claims 5, 6, 7 and 9 under 35 U.S.C. 112 second paragraph made in paragraph 11 of the office action mailed December 22, 2003 is withdrawn in view of applicants' amendments.

7. Rejection of claims 1-11 under 35 U.S.C. 103(a) made in paragraph 15 of the office action mailed December 22, 2003 is withdrawn in view of applicants' amendments.

Rejections Maintained

8. Rejection of claims 1-11 under 35 U.S.C. 112 first paragraph made in paragraph 9 of the office action mailed December 22, 2003 is maintained.

The rejection was as stated below:

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition inducing immune response against certain pathogens, does not reasonably provide enablement for a vaccine for inducing immune response against all pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case claims 1-11 are very broad and drawn to a vaccine. The only given example in the specification is in pages 11 and 14, mentioning the production of antigens for certain species of malaria and anthrax.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicants' invention is not enabled for the prevention, amelioration, or treatment of infectious diseases. And one skilled in the art will not be able to make/and or use the invention without undue experimentation commensurate in scope with the claims.

Applicants argue that the invention relates to the development of effective and long lasting vaccines incorporating nucleic acid encoding antigen, such as plasmid DNA, by encapsulating the DNA with a mucoadhesive controlled released particulate formulation. The specification teaches the use of vaccine composition to induce an immune response against pathogens. Applicants further argue that the prior art teaches the use of DNA production of vaccines against a vast array of disease.

Applicants' arguments have been fully considered but they are not persuasive because the specification, while being enabling for a composition inducing immune response against certain pathogens, does not reasonably provide enablement for a vaccine for inducing immune response against all pathogens. The claims are very broad and drawn to a vaccine, which encompasses any pathogen. The specification fails to teach a skilled artisan how to administer the claimed composition for immune protection. The specification presents a paper protocol in this regard.

The specification has not taught a skilled artisan how to use the invention as presently claimed. Applicants have not shown or disclosed a correlation between in vitro and in vivo studies or that there are animal models that correlate to human (i.e. person) efficacy. Applicants' specification fails to provide guidance to the skilled artisan on the parameters for DNA vaccine for the breadth of the claimed invention. Numerous factors complicate the DNA vaccine therapy art, which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated. Additionally, the specification does not provide any working examples which enable the claimed invention. Nor does the specification provide any guidance to the skilled artisan on how to make and use genetic constructs of all pathogens which would result in the desired effect. Even assuming that an effective genetic material is constructed, it is not evident that enough cells can be transfected to provide any therapeutic benefit. Therefore, even if the specification enabled the construction of the gene delivery vehicle comprising a cell targeting element, in the absence of particular guidance, the artisan would have been required to develop *in vivo* and *ex vivo* means of practicing the claimed methods and such development in the nascent and unpredictable gene therapy art would have been considered to have necessitated undue experimentation on the part of the practitioner.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the

invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

9. Rejection of claims 1-5 and 8-11 under 35 U.S.C. 102 (b) made in paragraph 13 of the office action mailed December 22, 2003 is maintained.

The rejection was as stated below:

Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Hagan Derek (Journal of Pharmacy and Pharmacology, Vol. 50, No. 1, pp.1-10, 1998).

The claims are drawn a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer.

O'Hagan Derek teaches a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen in a biodegradable polymer (see abstract). O'Hagan teaches poly (lactide-co-glycolide) a biodegradable polymer (page 6). O'Hagan teaches a variety of pathogens including malaria and *Helicobacter pylori* (**see** pages 2 and 3). O'Hagan teaches encapsulation (page6), adjuvants (page 5) particulates less than 5 micron and greater than 10 micron (see page 6). O'Hagan teaches mucosal immunization including nasal and oral (page 4). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art (i. e., that the composition of prior art does not possess the same material structure and functional

characteristics of the claimed composition). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants argue that O'Hagan discloses the use of biodegradable microparticles and encapsulation of antigens into poly (lactide-co-glycolide) particles. However, O'Hagan does not teach that the formulation is mucoadhesive, which enhances the effectiveness of the vaccine.

Applicants' arguments have been fully considered but they are not persuasive because O'Hagan teaches that mucosal administration of the vaccine which enhances the effectiveness of the vaccine (see abstract). O'Hagan teaches all the limitations of claimed invention. Limitations such as mucoadhesiveness of the formulation will be an inherent property of a microparticle formulated for mucosal delivery.

Conclusions

10. No claims are allowed.

11. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

June 13, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER